



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Secretary's Advisory Committee on Heritable Disorders in Newborns and Children

Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463, codified at 5 U.S.C. App. 2), notice is hereby given of the following meeting:

**Name:** Secretary's Advisory Committee on Heritable Disorders in Newborns and Children

**Dates and Times:** September 13, 2012, 8:30 a.m. to 6:00 p.m.  
September 14, 2012, 8:30 a.m. to 2:30 p.m.

**Place:** Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Room 800  
Washington, D.C. 20201

**Status:** The meeting is open to the public, but seating will be limited by the space available.

Security at the Humphrey building has requested that the public register for the meeting by September 11, 2012. See

<http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders> for a link to register

for the meeting. Please have a government I.D. for the meeting. For directions to the meeting, please visit <http://www.hhs.gov/about/hhhmap.html>.

**Purpose:** The Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC), as authorized by Public Law 106-310, which added section 1111 of the Public Health Service Act, codified at 42 U.S.C. 300b-10, was established by Congress to advise the Secretary of the Department of Health and Human Services with the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. The SACHDNC's recommendations regarding additional conditions/inherited disorders for screening that have been adopted by the Secretary are included in the Recommended Uniform Screening Panel (RUSP) that constitutes part of the comprehensive guidelines supported by the Health Resources and Services Administration. Pursuant to section 2713 of the Public Health Service Act, codified at 42 U.S.C. 300gg-13, non-grandfathered health plans are required to cover screenings included in the comprehensive guidelines without charging a co-payment, co-insurance, or deductible for plan years (i.e., policy years) beginning on or after the date that is one year from the Secretary's adoption of the screening. The SACHDNC also provides advice and recommendations concerning grants and projects authorized under section 1109 of the Public Health Service Act (42 U.S.C. 300b-8).

**Agenda:** The meeting will include: (1) updates on newborn screening case definitions and newborn screening quality indicators; (2) updates from the Nomination and Prioritization Workgroup and the Condition Review Workgroup regarding the final condition review matrix, Adrenoleukodystrophy, and Pompe Disease; (3) presentations on the National Institutes for Health's Ethical, Legal, and Social Implications Research Program, HRSA-funded prenatal

family history project, and the Institute of Medicine meeting summary on assessing the economics of genomic medicine; (4) reports on the continued work of the Advisory Committee's subcommittees on Laboratory Standards and Procedures, Follow-up and Treatment, and Education and Training; (5) workgroup reports on the second screen study, and carrier screening; and (6) CDC's Morbidity and Mortality Weekly Report on laboratory practices for genetic testing and newborn screening. Tentatively, the SACHDNC is expected to review and/or vote on the following items, none of which currently involve votes to add conditions to the RUSP: (1) Adrenoleukodystrophy – Nomination and Prioritization Report; (2) Condition Review Matrix; (3) Second Screen Study from CDC; and (4) the Morbidity and Mortality Weekly Report on Good Laboratory Practices for Biochemical Genetic Testing and Newborn Screening for Inherited Metabolic Disorder.

Proposed agenda items are subject to change as priorities dictate. The agenda, Committee Roster, Charter, presentations, and meeting materials are located at the homepage of the Advisory Committee's website at

<http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders>

**Public Comments:** Members of the public can submit written comments and/or present oral comments during the public comment periods of the meeting. All comments, whether oral or written, are part of the official Committee record and will be available for public inspection and copying. Written comments should be emailed or received by Thursday, September 6, 2012 to Debi Sarkar, Maternal and Child Health Bureau, Health Resources and Services Administration, Parklawn Building, 5600 Fishers Lane, Room 18A-19, Rockville, Maryland 20857; email: [dsarkar@hrsa.gov](mailto:dsarkar@hrsa.gov). Comments may also be faxed to 301-480-1312. Those individuals who want to make oral comments are required to notify Debi Sarkar via email or regular mail by 5 P.M.

Eastern Daylight Time, Thursday, September 6, 2012. Notification is required in order to present oral comments, Oral comments will be heard on September 13, 2012. All written and oral comments should contain the name, address, telephone number, professional or business affiliation of the author, and topic of comment. Presentations of oral comments may be limited depending on the number of presenters. Individuals who are associated with groups having similar interests are requested to combine their comments and present them through a single representative. No audiovisual presentations are permitted, to ensure that all individuals who provided notification to make oral comments have an opportunity to present their comments.

**Contact Person:** Anyone interested in obtaining other relevant information or attendees that will require special accommodations should contact Debi Sarkar, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A-19, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; telephone: 301-443-1080; email: [dsarkar@hrsa.gov](mailto:dsarkar@hrsa.gov). More information on the Advisory Committee is available at <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders>.

Dated: August 6, 2012

Reva Harris

Acting Director, Division of Policy and Information Coordination

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